NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, Defendants.	**Civil Action No. 15-3324 (SRC)** **OPINION** (consolidated for discovery purposes with Civil Action Nos. 16-4918, 16-9035, 15-3327, 16-4921, 15-3326, and 16-4920)
HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN, INC., Defendants.	
HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC., Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS INC., Defendants.	

CHESLER, U.S.D.J.

This matter comes before this Court on the motion for summary judgment of invalidity by Defendants Dr. Reddy's Laboratories Inc., Dr. Reddy's Laboratories Ltd., Mylan Inc., Mylan Laboratories Limited, and Mylan Pharmaceuticals Inc. (collectively, "Defendants.") Defendants move for summary judgment of invalidity of U.S. Patent Nos. 9,220,698 (the "'698 patent") and 9,393,208 (the "'208 patent") on the ground of indefiniteness. Plaintiffs Horizon Pharma, Inc., Horizon Pharma USA, Inc., and Pozen Inc. (collectively, "Plaintiffs") have opposed the motion. For the reasons that follow, the motion will be granted.

These cases arise from Hatch-Waxman litigation regarding patents related to the drug Vimovo®. Plaintiffs hold the patents and the various Defendants are pharmaceutical companies which have filed ANDA applications to produce generic versions. Both patents at issue disclose methods of treatment using pharmaceuticals containing naproxen and esomeprazole. Both patents have only one independent claim, which is claim 1 in each patent.

Defendants move for summary judgment of invalidity on the ground of indefiniteness. Claim 1 of the '698 patent is representative:[1]

> A method for treating osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis comprising orally administering to a patient in need thereof an AM unit dose form and, 10 hours (.+-.20%) later, a PM unit dose form, wherein:
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> the AM and PM unit dose forms each comprises: naproxen, or a pharmaceutically

[1] Claim 1 of the '208 patent is quite similar. During the Markman briefing, at the Markman hearing, and in the present briefing, the parties have uniformly treated claim 1 of the '698 patent as representative of the independent claims in both patents. No one has contended that claim 1 of the '698 patent differs materially from claim 1 of the '208 patent with regard to the "target" claim language at issue on this motion. This Court will therefore focus in this opinion, as it did in the Markman opinion, on claim 1 of the '698 patent, but will draw conclusions about the first claims of both patents.

> acceptable salt thereof, in an amount to provide 500 mg of naproxen, and esomeprazole, or a pharmaceutically acceptable salt thereof, in an amount to provide 20 mg of esomeprazole; said esomeprazole, or pharmaceutically acceptable salt thereof, is released from said AM and PM unit dose forms at a pH of 0 or greater,
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> the AM and PM unit dose forms target:
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> i) a pharmacokinetic (pk) profile for naproxen where: a) for the AM dose of naproxen, the mean C.sub.max is 86.2 .mu.g/mL (.+-.20%) and the median T.sub.max is 3.0 hours (.+-.20%); and b) for the PM dose of naproxen, the mean C.sub.max is 76.8 .mu.g/mL (.+-.20%) and the median T.sub.max is 10 hours (.+-.20%); and ii) a pharmacokinetic (pk) profile for esomeprazole where: a) for the AM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the AM dose is administered to 10 hours (.+-.20%) after the AM dose is administered (AUC.sub.0-10,am) is 1216 hr*.mu.g/mL (.+-.20%), b) for the PM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the PM dose is administered to 14 hours (.+-.20%) after the PM dose is administered (AUC.sub.0-14,pm) is 919 hr*.mu.g/mL (.+-.20%), and c) the total mean area under the plasma concentration-time curve for esomeprazole from when the AM dose is administered to 24 hours (.+-.20%) after the AM dose is administered (AUC.sub.0-24) is 2000 hr*.mu.g/mL (.+-.20%);
>
> and the AM and PM unit dose forms further target a mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state that is at least about 60%.

Defendants contend that the claim language involving "target" is indefinite. Claim 1 contains two "target" clauses, the first of which begins with, "the AM and PM unit dose forms target," and the second of which begins with, "and the AM and PM unit dose forms further target." These shall both be referred to as "the target clauses."

In the Markman Opinion, this Court construed "target" to mean "set as a goal," but reserved decision on the issue of whether the target clauses operate as claim limitations. Defendants had contended that the target clauses do not limit the claims, while Plaintiffs posited the contrary. Although Defendants still contend that the target clauses are not limiting, they make this motion based on the contingency that this Court might rule in Plaintiffs' favor in

finding that the target clauses limit the claims. The parties agree that this issue is the threshold issue for the present motion: if this Court decides that the target clauses are not claim limitations, the motion is moot. Thus, this Court begins with the question of whether the target clauses are claim limitations. The parties did not rebrief this issue, and so the Court considers the arguments presented during the Markman proceeding.

During the Markman proceeding, Defendants argued that the target clauses do not limit the claims because they merely recite intended results of the claimed method, citing the Federal Circuit's decision in Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001). In BMS, the Federal Circuit held that the preamble of a method claim did not operate as a claim limitation on these grounds: "[W]e agree with the defendants that this language is only a statement of purpose and intended result. The expression does not result in a manipulative difference in the steps of the claim." Id. Defendants also cite Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1378 (Fed. Cir. 2005), in which the Federal Circuit affirmed the district court's decision that a term within the body of the claim, "in a stabilizing amount," was not limiting because it only described the intended result of a method step.

Plaintiffs argue that the target clauses limit the claims for several reasons, one of which is quite strong: the applicants clearly treated them as such during prosecution. Plaintiffs point to the response to final office action, dated September 25, 2015, filed by the applicants. (Krumplitsch Dec. Ex. K.) Here, the applicants responded to the examiner's rejection of various claims, including claim 19, which matured into claim 1 of the '698 patent, for obviousness over Hassan-Alin in view of Plachetka. (Id. at PZC_00031651.) The applicants argued:

> To establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art. . . Once again, the examiner has not

addressed at least the following highlighted claim features:

(Id.) The applicants then quoted claim 19 in its entirety, highlighting all the claim text that followed the first instance of "target." (Id. at PZC_00031651-52.) The applicants then wrote: "There simply is no question, on the record, that the cited art lacks any teaching or suggestion of these features." (Id. at PZC_00031652.)

The Federal Circuit has held: "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002). Although the target clauses are not preambles, this principle applies. The prosecution history shows that the applicants relied on the target clauses to distinguish the claimed invention from the prior art. To overcome an obviousness rejection, the applicants argued that the prior art did not teach or suggest the "features"[2] contained in the target clauses. This demonstrates that the applicants used the target phrases to define, in part, the claimed invention. The target phrases limit the claims.

The specification supports this conclusion. It states, in relevant part:

> Over 15 million Americans take nonsteroidal anti-inflammatory drugs (NSAIDs) each day as a treatment for pain or inflammation. Unfortunately, many of these NSAIDs are associated with a high incidence of gastrointestinal complications . . . A major factor contributing to the development of gastrointestinal lesions appears to be the presence of acid in the stomach and upper small intestines.
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> During recent years, attempts have been made to reduce the gastrointestinal risk associated with taking NSAIDs by administering agents that inhibit stomach acid

[2] The use of the word "features," itself, indicates that the applicants understood the stated characteristics to be distinctive and important.

> secretion, such as, for example, proton pump inhibitors with the NSAID. For example, U.S. Pat. No. 6,926,907 is directed to at least one drug dosage form comprising a proton pump inhibitor that raises the pH of a patient's gastrointestinal tract, followed by an NSAID. This, and similar, formulations can be effective in improving NSAID tolerability through dosages of esomeprazole and naproxen that produce the desired pharmacodynamic response and pharmacokinetic values. Parameters that may influence the desired pharmacodynamic response and pharmacokinetic values include, but are not limited to, for example, the dosage of each; extent of drug absorption; extent of drug distribution, and the duration of drug administration.
>
> There is a need for a clinically effective therapy that delivers to a patient in need thereof a pharmaceutical composition in a unit dose form comprising naproxen, or pharmaceutically acceptable salt thereof, and esomeprazole, or pharmaceutically acceptable salt thereof, for a duration sufficient to achieve an instragastric pH of about 4 or greater and a plasma level of naproxen that is efficacious.
>
> In one aspect, the disclosure is directed to a method for delivering a pharmaceutical composition to a patient in need thereof, comprising: administering to said patient a pharmaceutical composition in unit dose form comprising naproxen, or pharmaceutically acceptable salt thereof, and esomeprazole, or pharmaceutically acceptable salt thereof, wherein said esomeprazole, or pharmaceutically acceptable salt thereof, is released from said unit dose form at a pH of from about 0 or greater to target: a mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state of at least about 41%.

‘698 patent, col.1 ll.19-59. In this passage, the specification places the invention in the context of the prior art and the problem to be solved. The second-to-last paragraph describes the problem to be solved, in short, as a need for a pharmaceutical composition comprising naproxen and esomeprazole that delivers these components “for a duration sufficient to achieve an instragastric pH of about 4 or greater and a plasma level of naproxen that is efficacious.” ‘698 patent, col.1 ll.46-48. The next paragraph describes one aspect of the invention as having release characteristics that target a solution to the part of the problem just pointed out. Now compare the second target clause in claim 1:

> and the AM and PM unit dose forms further target a mean % time at which

> intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state that is at least about 60%.

This claim language clearly relates to the statement of the problem to be solved, and also to the statement of that aspect of the invention which attempts to implement a solution to that problem. It refers to a significant aspect of what the inventor actually invented. See Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.") In the context of the inquiry into whether a preamble phrase limits the claim, the Federal Circuit has held: "The effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). It is unmistakable that the second target clause derives from what the inventors state they actually invented and attempts to "define, in part, the claimed invention." Catalina, 289 F.3d at 808.

The intrinsic evidence contained in the prosecution history and the specification demonstrates that the target clauses are claim limitations. Having resolved that issue, the Court finds that the motion for summary judgment is not moot, but is now ripe for consideration.

Defendants move for summary judgment of invalidity of the '698 and '208 patents on the ground that the claims are indefinite due to the target clauses. In short, Defendants argue that, given this Court's construction of "target" as "set as a goal," the "patents provide no guidance regarding how often, if ever, the recited ranges must be met or how close one must come to those ranges to infringe the asserted claims." (Defs.' Br. 2.)

The parties do not dispute the applicable legal standard: "a patent is invalid for

indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014). Indefiniteness is a question of law, which may rely on subsidiary determinations of underlying facts. Akzo Nobel Coatings, Inc. v. Dow Chem. Co., 811 F.3d 1334, 1343 (Fed. Cir. 2016). Patents are presumed to be valid; the challenger bears the burden of establishing invalidity by clear and convincing evidence. 35 U.S.C. § 282(a); Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95 (2011).

Because this Court construed "target" to mean, "set as a goal," this requires that the PK and PD profiles stated in the target clauses define the goals to be set. Plaintiffs argue, in essence, that those profile definitions are quite clearly delineated, but that misses the problem. The fact that a goal is clearly defined does not mean that the act of targeting that goal is clearly defined, and this is the crux of the definiteness problem here. The fundamental difficulty is that both key phrases here are incomprehensible: "the AM and PM unit dose forms target:" and "the AM and PM unit dose forms further target." It is not possible to comprehend what these phrases mean, because pills cannot be said to set goals. In ordinary usage, we understand a goal to be something that people, or perhaps living creatures, set; inanimate objects set no goals.

Moreover, it would be of no help to Plaintiffs to say, well, we know what the applicants were trying to say, and it is the physician treating the patient who sets these goals. There are two problems with this. First, that is not what the patentees wrote, and this Court will not redraft the claims to preserve their validity. See Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 799 n.6 (Fed. Cir. 1990) ("Nothing in any precedent permits judicial redrafting of claims.")

Second, even if the claims were so rewritten, this change alone would not suffice to make them comprehensible. Even if – for the sake of discussion only – there was some valid way to construe the claims to mean that the treating physician sets these goals, it still fails to inform with reasonable certainty about the scope of the invention.

The Supreme Court has stated that a patent rewards innovation with a temporary monopoly: "The monopoly is a property right; and like any property right, its boundaries should be clear." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 730 (2002). Thus, a patent must inform the public of those boundaries: "A patent holder should know what he owns, and the public should know what he does not." Id. at 731. The problem here is that the target clauses fail to draw clear boundaries. Suppose you are a physician who has obtained pills that provide 500 mg of naproxen and 20 mg of esomeprazole, and you want to treat a patient suffering from osteoarthritis, but you want to avoid infringing the '698 patent. How do you determine the boundary for what you may legally do and what you may not? If we understand these target clauses to mean that the pills cannot set particular goals, you can relax about infringing, because your pills will never set any goals. If we understand these target clauses to mean that you, the treating physician, cannot yourself set treatment goals for PK and PD outcomes that fall within the claimed values, do you now know, with reasonable certainty, what you may permissibly do and what you may not? This Court sees no way that defining the goals for a method can, without more, inform the public of how to act to avoid infringement.[3] This is

[3] This is not a mere bicker over the meaning of one word, "target;" this Court truly cannot discern what the claimed method is. The method begins with orally administering to a patient in need a pharmaceutical that provides 500 mg of naproxen and 20 mg of esomeprazole – that method step is clear. The remainder of claim 1, the two target clauses, do not appear to be cognizable as method steps. Instead, the most reasonable inference is that they reflect attributes

Defendants' point, and this Court agrees.

To make this analysis less abstract, consider Defendants' argument that "claims that target PK and PD values as a goal for the dosage forms lack the 'objective boundaries' required under § 112, ¶ 2 because they provide no discernable standard for how far a particular formulation administered to any given patient or group of patients can stray from the stated goals and still infringe the claims." (Defs.' Br. 10.) Had this Court agreed with Plaintiffs during claim construction that "target" meant "produce," it would be clear enough that you, the physician wanting to avoid infringing the '698 patent, must somehow take care to ensure that your naproxen/esomeprazole pills do not achieve blood levels and intragastric pH levels in the treated patient that fall within the scope of the PK and PD characteristics defined in the claim. It would be clear that, to avoid infringing claim 1 of the '698 patent, you must avoid effecting these particular, defined outcomes. Because, however, this Court concluded that "target" means "set as a goal," it is not possible to discern what the target clauses are telling you to do or not do. Defendants are correct that the patent provides no discernable standard for drawing the line that distinguishes infringing acts from noninfringing ones – because the target clauses are incomprehensible. As the claim is written, you must take care that your pills do not set certain goals, which is nonsensical. Even if, somehow, we construe the claim to mean that the physician sets the goals, it appears that you, the treating physician, must avoid having a subjective intent to achieve the defined outcomes. This is neither comprehensible nor cognizable as a claim

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of the effect of the pharmaceutical on a population of patients. As already explained, this Court's construction of "target" precludes construing it as "produce." Because "target" does not mean "produce," the clauses which might define attributes of the pharmaceutical's effect are, effectively, left marooned, with no comprehensible connection to the administration step.

limitation: it simply cannot be that the question of infringement of a method patent turns on the mental state of the accused infringer, or of a pill that does not have one.

Plaintiffs' opposition to the motion for summary judgment fails principally because of two defects. First, Plaintiffs give only lip service to this Court's claim construction decision that "target" means "set as a goal." Plaintiffs' arguments reflect a total denial of this Court's rejection of their proposed construction, and are presented as if this Court had accepted, rather than rejected, their proposed construction. For example – and this goes to the heart of Plaintiffs' argument that the claims are definite –, Plaintiffs state: "If such a 'goal' or 'target' is not met, then an accused product does not infringe the asserted claims." (Pls.' Opp. Br. 6.) Plaintiffs thus continue to insist that "target" means "produce," and that everything is clear because the claim requires the accused infringer to meet the goal; there is no meaningful difference between this reading of the claim and the one this Court rejected during claim construction.

Second – and this flows from the first defect –, Plaintiffs repeatedly focus on the larger part of the target clauses which they contend is definite and not on the smaller portion which this Court finds indefinite. Consider, for example, the second target clause in claim 1 of the '698 patent:

> and the AM and PM unit dose forms further target a mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state that is at least about 60%.

This can be broken into two basic parts:

> "and the AM and PM unit dose forms further target"
>
> "a mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state that is at least about 60%."

The fact that the second part of the clause may be definite is a different issue from whether the

first part is indefinite. Plaintiffs focus on the second part and, generally, overlook the major problems with the first part.

In opposition, Plaintiffs make four different arguments. Plaintiffs first argue: "Defendants' arguments that the asserted claims are indefinite are premised on a mistaken reading of the Court's *Markman* Order: they focus on individual patients while ignoring the claims read in light of the patent specification." (Pls.' Opp. Br. 4.) This Court disagrees and finds that it is Plaintiffs who have made a mistaken reading of the claim construction decision. This Court made no decision about whether the target clauses describe PK and PD values for individual patients or for groups of patients. That issue was tangential to the claim construction disputes. In the decision, the Court referenced the parties' positions on this issue as it considered the meaning of "target," and nothing more.

Furthermore, because the section of Plaintiffs' opposition brief which makes this first argument is quite confused and contradictory, it is difficult to find the sense in this first argument. Plaintiffs begin by quoting the claim construction decision out of context:

> If Plaintiffs are correct in their contention that the PK and PD values in claim 1 are averages for a group, the claim, using this construction, makes sense: one administers the method to an individual patient with the goal of obtaining these values, on average, for a group of patients.

(Opinion & Order of November 14, 2017 at 11.) In the next line, Plaintiffs write: "The Court's explanation of the claimed PK and PD parameters above, is consistent with Plaintiffs' understanding, and renders the asserted claims definite." (Pls.' Opp. Br. 5.) It is difficult to interpret what Plaintiffs have really said here, since they have misread the decision and quoted it out of context. Consider the original quote in context. The Court was discussing Defendants' proposed construction of target, "to establish as a goal." (Opinion & Order of November 14,

2017 at 11.) The Court then wrote:

> If Plaintiffs are correct in their contention that the PK and PD values in claim 1 are averages for a group, the claim, using this construction, makes sense: one administers the method to an individual patient with the goal of obtaining these values, on average, for a group of patients. From this perspective, the PK and PD profiles in claim 1 do not serve as limitations for the method, but as statements of a goal aspired to, but not met, for every patient.

(Id.) Among a number of problems, Plaintiffs have overlooked the word "if" that begins the first quoted sentence above. The word "if" signals the reader that what follows is contingent on the correctness of the predicate proposition, which has not been determined. This Court did not make any determination as to the correctness of that predicate.

Having misread the claim construction decision, it is difficult to figure out what Plaintiffs are agreeing to when they say that the Court's explanation of the PK and PD parameters is consistent with their understanding. *If* the quote is considered in context, it appears that Plaintiffs are saying that they agree that "the PK and PD profiles in claim 1 do not serve as limitations for the method, but as statements of a goal aspired to, but not met, for every patient." That would be contrary to their stated position, which is that they do serve as claim limitations.

What is clear in this section is that Plaintiffs contend that "the claims, read in light of the specification, refers [sic] to average PK and PD values derived from multiple individual patients." (Id.) This Court continues to take the position that it need not reach the question of whether this tangential contention is correct. *Even if* Plaintiffs are correct on this point, "target" is still indefinite, and quite possibly this makes the claim less comprehensible. Do Plaintiffs contend that claim 1 of the '698 patent should be understood to disclose a method of treating "a patient" that entails the pill or the physician targeting average PK and PD characteristics for some group of patients? How does this help make the claim comprehensible? As Defendants

argue, the patent still fails to teach how to draw the line to determine what to do to avoid infringing. What does their being averages have to do with ascertaining the meaning of "target" with reasonable certainty?

The indefiniteness problem here lies in the first element of the target clause, not the second: it is in the use of the word "target," not in the following language that states some definition of what the target is. The claim language delineating the target could be clear as day, and "target" would still be indefinite. Deciding whether or not the target values are averages from multiple patients has no impact on this problem.

Plaintiffs then write:

> While individual patients may fall outside the claimed range, the averages for the group of patients fall clearly within the claimed ranges. As Dr. Taft explains, "[t]he claims are as reasonably certain as they could be, given the variability in PK/PD values." (Ex. A, Taft Rebuttal Report, ¶ 78.)
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> Defendants also assert that the record provides no basis to identify "how much the results of such targeting can deviate from those goals and still fall under the claims." (ECF No. 119 at 16.) On the contrary, the claims themselves provide a clear basis to identify such deviation. As Dr. Taft explains, "[a] person of ordinary skill in the art would know that the PK and PD values in claim 1 of both patents are average values. Thus, a skilled artisan would be targeting ±20% of an average parameter." (Ex. A, Taft Rebuttal Report, ¶ 73.) The metes and bounds of the claims are clearly defined by claimed the range of ±20% of the average PK and PD values (i.e. Cmax, AUC, etc.).

(Pls.' Opp. Br. 7.) The proffered explanations from expert Dr. Taft do not help solve the problem of the meaning of "target." Dr. Taft does no more than say that the claim language clearly defines the bounds of the target. As already explained, this does not remedy the problem of the indefiniteness of the word "target," itself. Dr. Taft states: " a skilled artisan would be

targeting ±20% of an average parameter."[4] (Id.) Given that this Court has construed "target" to mean, "set as a goal," the Court interprets Dr. Taft's statement to be that "a skilled artisan would set as a goal ±20% of an average parameter." Even if Dr. Taft is correct, this still does not solve the problem raised by Defendants: the claim provides "no discernable standard for how far a particular formulation administered to any given patient or group of patients can stray from the stated goals and still infringe the claims." (Defs.' Br. 10.)

Plaintiffs' second argument challenges Defendants' contention that it is problematic that the claim does not specify who is doing the targeting:

> As discussed above, the metes and bounds of the claims are definite and clear. A dosage form of the claimed composition that results in a group of individuals with average PK and PD values falling within the claimed parameters infringes the asserted claims . . .

(Pls.' Opp. Br. 8.) This argument rests on a rejected predicate. Plaintiffs argue as if the Court had adopted their proposed construction of "target," which was "produce." The Court rejected Plaintiffs' proposal that the claim language should be understood to "produce" or "result" in the PK and PD profiles. Plaintiffs again have failed to accept this Court's construction of the meaning of "target."

Third, Plaintiffs argue that factual disputes preclude a grant of summary judgment. The factual dispute, Plaintiffs contend, arises from the fact that the parties' experts disagree. Specifically, Plaintiffs quote their expert, Dr. Taft: "the asserted claims provide reasonable notice to others in the field of what actions may infringe the claims." (Pls.' Op. Br. 8.) That is not a factual assertion but a legal conclusion. Indefiniteness is a question of law, which may rely

[4] Note that Dr. Taft has just implicitly redrafted the claim, which, as written, states that the dose form does the targeting, not the physician.

on underlying factual determinations. Plaintiffs point to a conclusion about the ultimate legal issue, but not to any particular underlying factual disputes. The Court need not credit conclusory statements by experts and need not find such statements sufficient to raise material factual disputes. Stumbo v. Eastman Outdoors, Inc., 508 F.3d 1358, 1365 (Fed. Cir. 2007) ("We have repeatedly held that such cursory conclusions will not withstand summary judgment"); Imperial Tobacco, Ltd. v. Philip Morris, Inc., 899 F.2d 1575, 1581 (Fed. Cir. 1990) ("As this court has frequently said in connection with motions for summary judgment, a conclusory statement on the ultimate issue does not create a genuine issue of fact"); SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1116 (Fed. Cir. 1985) ("The party opposing the motion must point to an evidentiary conflict created on the record; mere denials or conclusory statements are insufficient.") Plaintiffs have failed to point to an evidentiary conflict created in the record. Dr. Taft's legal conclusion does not preclude the entry of judgment as a matter of law.

Lastly, Plaintiffs contend that Defendants cannot both assert that the target clauses are non-limiting and that they are indefinite. Plaintiffs ignore that they have consistently argued that the target clauses limit the claims. Now that this Court has agreed, Plaintiffs are in no position to argue that the Court's resolution should not be based on that decision. In any case, this point is now moot. Defendants argued in the alternative, and this Court has now decided that the target clauses limit the claims. "[P]arties can certainly argue in the alternative." Golden Bridge Tech., Inc. v. Apple Inc., 758 F.3d 1362, 1369 (Fed. Cir. 2014).

Defendants have shown that they are entitled to judgment as a matter of law of invalidity of the patents at issue. This Court finds that Defendants have shown, by clear and convincing evidence, that claim 1 of the '698 patent and claim 1 of the '208 patent are invalid for

indefiniteness: these claims, read in light of the specification delineating the patents, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention. Plaintiffs have failed to demonstrate that any factual disputes preclude the entry of judgment as a matter of law.

Claim 1 is the only independent claim in the '698 patent, and claim 1 is the only independent claim in the '208 patent. Because the Court has found that claim 1 in both patents is invalid for indefiniteness, and because all remaining claims depend on claims now found to be invalid, all claims in both the '698 and '208 patents are invalid. Defendants' motion for summary judgment will be granted. Judgment on Defendants' affirmative defense of patent invalidity under 35 U.S.C. § 112 will be entered in Defendants' favor. All claims of U.S. Patent Nos. 9,220,698 and 9,393,208 will be declared invalid due to indefiniteness, pursuant to 35 U.S.C. § 112.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: November 19, 2018